DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

B. Braun Medical, Incorporated
Ms. Nancy Skocypec
Senior Regulatory Affairs Specialist
901 Marcon Boulevard
Allentown, Pennsylvania 18109

October 8, 2013

Re: K130857
Trade/Device Name: Prontosan® Wound Gel X
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 14, 2013
Received: August 19, 2013

Dear Ms. Skocypec:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K130857

Device Name: Prontosan® Wound Gel X

Indications For Use:

Rx: Prontosan® Wound Gel X is indicated for the management of ulcers (including diabetic foot and leg ulcers and pressure ulcers), 1st and 2nd degree burns, partial and full thickness wounds, large surface area wounds and surgical incisions.

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K130857

Device Name: Prontosan® Wound Gel X

Indications For Use:

OTC: Prontosan Wound Gel X is indicated for the management minor cuts, minor lacerations, minor burns (1st degree burns), and abrasions.

Prescription Use _____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

5. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

DATE: August 14, 2013

SUBMITTER:
B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
610-266-0500

Contact: Nancy Skocypec, Regulatory Affairs Manager
Phone: (610) 596-2796
Fax: (610) 266-4962
E-mail: nancy.skocypec@bbraun.com

TRADE NAME: Prontosan® Wound Gel X

COMMON NAME: Wound dressing

Device Classification: Unclassified, Product Code FRO

PREDICATE DEVICE: Silver Shield™ Antimicrobial Skin and Wound Gel (K062212)

PolyFIT™+ Absorbing Antimicrobial Dressings, PolyFIT™+ High Absorbing Antimicrobial Dressings (K121522)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION
Prontosan Wound Gel X is a ready to use, clear, odorless, amorphous hydrogel wound dressing that helps maintain a clean, moist wound environment. It is intended as a barrier to resist microbial colonization within the dressing and reduce microbial penetration through the dressing. The gel matrix includes the preservative, polyhexanide, a viscosity modifying agent and a betaine surfactant. GelX is supplied sterile in blind ended, heat sealed polyfoil 250g tubes fitted with PP screw caps.

INDICATIONS FOR USE
Rx - Prontosan® Wound Gel X is indicated for the management of ulcers (including diabetic foot and leg ulcers and pressure ulcers), 1st and 2nd degree burns, partial and full thickness wounds, large surface area wounds and surgical incisions.

SUBSTANTIAL EQUIVALENCE
B. Braun Medical Inc's. Prontosan Wound Gel X is substantially equivalent to the predicate devices having similar indications for use, technological properties and performance.

TECHNICAL CHARACTERISTICS
Prontosan Wound Gel X has similar physical and technical characteristics to the predicate devices.

PERFORMANCE DATA

Biocompatibility and performance testing was performed with Prontosan Wound Gel X to support substantial equivalence to the predicate devices. Biocompatibility testing was performed in accordance with ISO 10993-1. Performance testing completed included USP<51> and a Strike Through Barrier Test. Test results met the acceptance criteria.

CONCLUSION

Based on the results of biocompatibility and performance testing, the proposed Wound Gel X is considered substantially equivalent to the predicate devices and is safe and effective for its' intended use.

K130857

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